

0200  
Atty Dkt PP0926.105  
2300-0926.04  
PATENT

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Date

Patricia K. Danner  
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Huston et al.

Serial No.: 09/558,741

Filing Date: April 26, 2000

Title: BIOSYNTHETIC BINDING PROTEINS FOR IMMUNO-TARGETING



Group Art Unit: unassigned

Examiner: unassigned

TRANSMITTAL LETTER

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is an Information Disclosure Statement, including a Form PTO-1449. It is believed that no fee is due.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 18-1648.

Respectfully submitted,

Date: 25 May 2000

By: Gary R. Fabian  
Gary R. Fabian  
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Patricia L. Huston  
 Signature

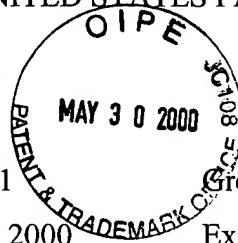
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**INFORMATION DISCLOSURE STATEMENT  
 UNDER 37 C.F.R. § 1.97**

Assistant Commissioner for Patents  
 Washington, D.C. 20231

Sir:

The information listed on the accompanying Form PTO-1449 may be material to the examination of the above-identified application. A completed Form PTO-1449 listing the references accompanies this paper.

All references are of record, or have been submitted in related application serial number 08/462,641 from which the present application claims priority under 35 U.S.C. §120. Thus, pursuant to C.F.R. §1.98(d), copies of the references are not included.

Applicants would appreciate the Examiner's initialing and returning the form to indicate that the references have been reviewed and made of record in the present application.

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information,

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protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

Date: 25 May 2000

By:

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FORM PTO-1449		ATTY DOCKET NO.: PP0926.105					
INFORMATION DISCLOSURE STATEMENT		APPLICANT: Huston et al. <i>ATTCP TO</i>					
8758 MAY 30 2000 PATENT & TRADEMARK OFFICE		Serial No.: 09/558,741 <i>#3</i>					
		FILING DATE: 4/26/00			GROUP: unassigned		
U.S. PATENT DOCUMENTS							
EXAM. INIT.	DOCUMENT NUMBER	TRADEMARK DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE	
100	AA 4,472,509	09/18/84	Gansow et al.	436	548		
	AB 4,479,930	10/30/84	Hnatowich	424	1.1		
	AC 4,753,894	06/28/88	Frankel et al.	436	548		
	AD 4,946,778	08/07/90	Ladner et al.	435	69.6		
100	AE 5,091,513	02/25/92	Huston et al.	530	387		
100	AF 5,132,405	07/21/92	Huston et al.	530	387.3		

FOREIGN PATENT DOCUMENTS							
EXAM. INIT.	DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY
BA	W085/03523	08/15/85	PCT				
BB	W088/09344	01/12/88	PCT				
BC	0502812 A1	09/09/92	EPO				
BD	W092/15682	09/17/92	PCT				
BE	W093/06217	04/01/93	PCT				

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.		FILING DATE:	GROUP:
CA	Saul et al. (1978) The Journal of Biological Chemistry, Vol. 253, No. 2, pp. 585-597, "Preliminary Refinement and Structural Analysis of the Fab Fragment from Human Immunoglobulin New at 2.0 A Resolution" ✓		
CB	Khaw et al. (1980) Science, Vol. 209, No. 4453, pp. 295-297, "Myocardial Infarct Imaging of Antibodies to Canine Cardiac Myosin with Indium-111-Diethylenetriamine Pentaacetic Acid" ✓		
CC	Kunkel (1985) Proc. Natl. Acad. Sci. Vol. 82, pp. 488-492, "Rapid and efficient site-specific mutagenesis without phenotypic selection" ✓		
CD	Chen et al. (1985) DNA, Vol. 4, No. 2, pp. 165-170, "Laboratory Methods Supercoil Sequencing: A Fast and Simple Method for Sequencing Plasmid DNA" ✓		
EXAMINER		DATE CONSIDERED	

**EXAMINER**

**DATE CONSIDERED**

FORM PTO-1449		ATTY DOCKET NO.: PP0926.105
INFORMATION DISCLOSURE STATEMENT		
EXAM. INIT.	APPLICANT: Huston et al.	
MAY 30 2000 PATENT & TRADEMARK OFFICE RECEIVED Serial No.: 09/558,741		FILING DATE: 4/26/00 GROUP: unassigned
CE	Bjorn et al. (1985) Cancer Research, Vol. 45, pp. 1214-1221, "Evaluation of Monoclonal Antibodies for the Development of Breast Cancer Immunotoxins"	
CF	Fisher et al. (1986) Journal of Clinical Oncology. Vol. 4, No. 6, pp. 929-941, "Ten-Year Results From the National Surgical Adjuvant Breast and Bowel Project (NSABP) Clinical Trial Evaluating the Use of L-Phenylalanine Mustard (L-PAM) in the Management of Primary Breast Cancer"	
CG	Satow et al. (1986) J. Mol. Biol., Vol. 190, pp. 593-604, "Phosphocholine Binding Immunoglobulin Fab McPC603 An X-ray Diffraction Study at 2.7 Å"	
CH	Amit et al. (1986) Science, Vol. 233, pp. 747-753, "Three-Dimensional Structure of An Antigen-Antibody Complex at 2.8 Å Resolution"	
CI	Sheriff et al. (1987) Proc. Natl. Acad. Sci. USA, Vol. 84, pp. 8075-8079, "Three-dimensional structure of an antibody-antigen complex"	
CJ	Colman et al. (1987) Nature, Vol. 326, pp. 358-363, "Three-dimensional structure of a complex of antibody with influenza virus neuraminidase"	
CK	Bartlet et al. (1987) The Lancet, Vol. II, No. 8552, pp. 171-175, "Adjuvant Tamoxifen in the Management of Operable Breast Cancer: The Scottish Trial"	
CL	Aisner et al., (1987) Journal of Clinical Oncology, Vol. 5, No. 10, pp. 1523-1533, "Chemotherapy Versus Chemoimmunotherapy (CAF v CAFVP v CMF Each ± MER) for Metastatic Carcinoma of the Breast : A CALGB Study"	
CH	Huston et al. (1988) Proc. Natl. Acad. Sci., Vo. 85, pp. 5879-5883, "Protein engineering of antibody binding sites: Recovery of specific activity in an anti-digoxin single-chain Fv analogue produced in Escherichia coli"	
CN	Sefton (1988) Trends in Genetics, Vol. 4, No. 9, pp. 247-248, "news about c-erb-B-2 and HER2"	
CO	Bird, et al. (1988) Science, Vol. 242, pp. 423-426, "Single-Chain Antigen-Binding Proteins"	
CP	Vogel et al. (1988) Biochemistry, Vol. 28, pp. 2961-2966, "Binding Domains and Epitopes in Platelet-Derived Growth Factor"	
CQ	Orlandi et al. (1989) Proc. Natl. Acad. Sci. USA, Vol. 86, pp. 3833-3837, "Cloning immunoglobulin variable domains for expression by the polymerase chain reaction"	
EXAMINER	DATE CONSIDERED	

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT		ATTY DOCKET NO.: PP0926.105
EXAM. INIT.	MAY 30 2000 PATENT & TRADEMARK OFFICE U.S. DEPARTMENT OF COMMERCE	
	Serial No.: 09/558,741	
	FILING DATE: 4/26/00	GROUP: unassigned
CR	Ring et al. (1989) <u>Cancer Research</u> Vol. 49, No. 11, pp. 3070-3080, "Distribution and Physical Properties of BCA200, a M 200,000 Glycoprotein Selectively Associated with Human Breast Cancer"	
CS	Dillman (1989), <u>Annals of Internal Medicine</u> , Vol. 111, pp. 592-603, "Monoclonal Antibodies for Treating Cancer"	
CT	Glockshuber et al. (1990) <u>Biochemistry</u> , Vol. 29, pp. 1362-1367, "A Comparison of Strategies to Stabilize Immunoglobulin F <sub>v</sub> Fragments"	
CU	Queen et al. (1989) <u>Proc. Natl. Acad. Sci.</u> , Vol. 86, pp. 10029-10033, "A humanized antibody that binds to the interleukin 2 receptor"	
CV	Hird et al. (1990) <u>Genes and Cancer</u> , pp. 183-189, "Immunotherapy with Monoclonal Antibodies"	
CW	Batra et al. (1990) <u>The Journal of Biological Chemistry</u> , Vol. 265, No. 25, pp. 15198-15202, "Anti-Tac(Fv)-PE40, a Single Chain Antibody Pseudomonas Fusion Protein Directed at Interleukin 2 Receptor Bearing Cells"	
CX	McGuire et al. (1990) <u>Journal of the National Cancer Institute</u> , Vol. 82 No. 12, pp. 1006-1015, "How to Use Prognostic Factors in Axillary Node-Negative Breast Cancer Patients"	
CY	Shealy et al. (1990) <u>The Journal of Nuclear Medicine</u> , Vol. 31, No. 5, Abstract Book Proceedings of the 37th Annual Meeting, "Characterization and Biodistribution of Tc-99m Labeled Single Chain Antibody Fv Fragment (sFv)"	
CZ	Colcher et al. (1990) <u>J. Natl. Cancer Inst.</u> , Vol. 82, No. 14, pp. 1192-1197, "In Vivo Tumor Targeting of a Recombinant Single-Chain Antigen-Binding Protein"	
CCA	Batra et al. (1990) <u>Biochemical and Biophysical Research Communications</u> Vol. 171, No. 1, pp. 1-6, "TGFa-anti-Tac(Fv)-PE40: A Bifunctional Toxin Cytotoxic for Cells with EGF or IL2 Receptors"	
CCB	Tai et al. (1990) <u>Biochemistry</u> , Vol. 29, pp. 8024-8030, "A Bifunctional Fusion Protein Containing Fc-Binding Fragment of B of Staphylococcal Protein A Amino Terminal to Antidigoxin Single-Chain Fv"	
CCC	Huston et al. (1990) <u>Bispecific Antibodies and Targeted Cellular Cytotoxicity</u> , Second International Conference, pp. 201-206, "Bifunctional Single-Chain Fv Fusion Proteins"	
CCD	Huston et al. (1990) <u>Academic Press, Inc., Methods in Enzymology</u> , Vol. 203, pp. 46-89, "Protein Engineering of Single-Chain Fv Analogs and Fusion Proteins"	
EXAMINER	DATE CONSIDERED	

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT		ATTY DOCKET NO.: PP0926.105
EXAM. INIT.	APPLICANT: Huston et al. Serial No.: 09/558,741 FILING DATE: 4/26/00	
		GROUP: 1642 <u>unassigned</u>
CCE	Whitlow et al. (1991), Methods: A Companion to Methods in Enzymology, Vol. 2, No. 2, pp. 97-105, "Single-Chain Fv Proteins and Their Fusion Proteins"	
CCF	Nedelman et al. (1991) Abstract Form for Scientific Papers, No. 32070 The Society of Nuclear Medicine 38th Annual Meeting, "Rapid Infarct Imaging with a New Tc-99m Antimyosin sFv Fragment: Evaluation in Acute Myocardial Infarction in Dogs"	
CCG	Waldmann (1991) Science, Vol. 252, pp. 1657-1662, "Monoclonal Antibodies in Diagnosis and Therapy"	
CCH	Clackson et al. (1991) Nature, Vol. 352, pp. 624-628, "Making antibody fragments using phage display libraries"	
CCI	Ring et al. (1991) Molecular Immunology, Vol. 28, No. 8, pp. 915-917, "Identity of BCA200 and c-erbB-2 Indicated by Reactivity of Monoclonal Antibodies with Recombinant c-erbB-2"	
CCJ	Milenic et al. (1991) Cancer Research, Vol. 51, pp. 6363-6371, "Construction, Binding Properties, Metabolism, and Tumopr Targeting of a Single-Chain Fv Derived from the Pancarcinoma Monoclonal Antibody CC49"	
CCK	Wels et al. (1992) J. Steroid Biochem. Molec. Biol., Vol. 43, No. 1-3, pp. 1-7, "Diminution of Antibodies Directed Against Tumor Cell Surface Epitopes: A Single Chain Fv Fusion Molecule Specifically Recognizes the Extracellular Domain of the c-erbB-2 Receptor"	
CCL	Pack et al. (1992) Biochemistry, Vol. 31, No. 6, pp. 1579-1584, "Miniantibodies: Use of Amphipathic Helics To Produce Functional, Flexibility Linked Dimeric Fv Fragments with High Avidity in Escherichia coli"	
CCM	Yokota et al. (1992) Cancer Research, Vol. 52, pp. 3402-3408, "Rapid Tumor Penetration of a Single-Chain Fv and Comparision with Other Immunoglobulin Forms"	
CCN	Cumber et al. (1992) The Journal of Immunology, Vol. 149, No. 1, pp. 120-126, "Comparative Stabilities in Vitro and in Vivo of a Recombinant Mouse Antibody FvCys Fragment and a bisFvCys Conjugate"	
CCO	Wels et al. (1992) Biotechnology, Vol. 10, pp.1128-1132, "Construction, Bacterial Expression and Characterization of a Bifunctional Single-Chain Antibody-Phosphatase Fusion Protein Targeted to the Human ERBB-2 Receptor"	
CCP	Schott et al. (1992) Cancer Research, Vol. 52, pp. 6413-6417, "Differential Metabolic Patterns of Iodinated versus Radiometal Chelated Anticarcinoma Single-Chain Fv Molecules"	
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INFORMATION DISCLOSURE STATEMENT		APPLICANT: Huston et al.	
		Serial No.: 09/558,741	
EXAM. INIT.	O I P E MAY 30 2000 PATENT		1642 FILING DATE: 4/26/00 GROUP: unassigned
CCQ	Wels et al. (1992) Cancer Research, Vol. 52, pp. 6310-6317, "Selective Inhibition of Tumor Cell Growth by a Recombinant Single-Chain Antibody Toxin Specific for the erbB-2 Receptor"		
CCR	Nedelman et al. (1993) The Journal of Nuclear Medicine, Vol. 34, pp. 234-241, "Rapid Infarct Imaging with a Technitium-99m-Labeled Anti-myosin Recombinant Single-Chain Fv: Evaluation in a Canine Model of Acute Myocardial Infarction"		
CCS	Adams et al. (1993) Abstract, International Conference on Monoclonal Antibody Immunoconjugates for Cancer, "Demonstration of in vivo specificity of 125I-741F8 sFv, a single-chain Fv molecule"		
CCT	Huston et al. (1993) Immunotechnology, Proceedings of the 21st Federal of European Biochemical Societies Meeting, Dublin, pp. 47-60, "Single-chain immunotechnology of Fv analogues and fusion proteins"		
CCU	McCartney et al. (1993) Biotechnology, Advances in Gene Technology Protein Engineering and Beyond, Proceedings of the 1993 Miami Bio/Technology Winter Symposium, "Refolding of Single-Chain Fv with c-Terminal Cysteine (sFv'): Formation of Disulfide-Bonded Homodimers of Anti-c-erbB-2 and Anti-digoxin sFv"		
CCV	Huston et al. (1993) Intern. Rev. Immunol., Vol. 10, pp. 195-217, "Medical Applications of Single-Chain Antibodies"		
CCW	Adams et al. (May 1993) Abstract, The Tenth International Hammersmith Conference, "Demonstration of in vivo tumor specificity of monovalent and divalent forms of 125I-741F8 sFv, an anti-c-erbB-2 single-chain Fv molecule"		
CCX	Huston et al. (May 1993) Abstract for the 10th Hammersmith Meeting "Refolding and Characterization of single-chain Fv analogues having C-terminal cysteine (sFv): physicochemical behavior in vitro and tumor localization in vivo of monovalent sFv and bivalent (sFv) <sub>2</sub> species directed to the c-erbB-2 tumor antigen and digoxin"		
CCY	Holliger et al. (1993) Proc. Natl. Acad. Sci. USA, Vol. 90, pp. 6444-6448, "Diabodies: Small bivalent and bispecific antibody fragments"		
CCZ	Adams et al. (1993) Cancer Research, Vol. 53, pp. 4026-4034, "Highly Specific in Vivo Targeting by Monovalent and Divalent Forms of 741F8 Anti-c-erbB-2 Single-Chain Fv"		
CCCA	Jacobs (1991) Biotechnology 9:258-262.		
CCCB	Reichmann et al. (1988) Nature 332: 323-327.		
EXAMINER	DATE CONSIDERED		

FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT



ATTY DOCKET NO.: PP0926.105

APPLICANT: Huston et al.

Serial No.: 09/558,741

FILING DATE: 4/26/00

GROUP: 1642  
unassigned

## U.S. PATENT DOCUMENTS

EXAM. INIT.	DOCUMENT NUMBER	TRADEMARK DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
14	AG 5,258,498	11/02/93	Huston et al.	530	350	
15	AH 5,260,203	11/09/93	Ladner et al.	435	7223	
19	AI 5,571,894	11/05/96	Wels et al.			
20	AJ 5,587,458	12/24/96	King et al.			

## FOREIGN PATENT DOCUMENTS

EXAM. INIT.	DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	FILING DATE:	GROUP:
CCCC	Houston, Abstract from NIH Grant, Serial No. U01 CA51880-05.	
CCCD	Pluckthun (1992) "Mono- and Bivalent Antibody Fragments Produced in Escherichia coli: Engineering, Folding and Antigen Binding," <u>Immunological Reviews</u> , 130: 151-188.	
EXAMINER		DATE CONSIDERED